United States District Court for the District of New Jersey

Elizabeth Clarke Feher and Thomas Feher , Her Husband, Plaintiffs,	:	
vs.	:	Case No.
Zimmer, Inc., Zimmer Holdings, Inc. and Zimmer Orthopaedic Surgical Products, Inc.: Defendants	:	**Complaint and Jury Demand**

Jurisdiction and Venue

1. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332, because the amount in controversy as to Plaintiffs exceeds $75,000.00, exclusive of interests and costs, and because complete diversity exists between the parties, as Plaintiffs, Elizabeth Clarke Feher and Thomas Feher are citizens of Nutley, Essex County, New Jersey, which is different from the states where Defendants are all incorporated and have their principal places of business.

2. Venue is proper in this court pursuant to 28 U.S.C. § 1391 because a substantial part of the events giving rise to the claim occurred in this District where the Defendants are subject to the personal jurisdiction in accordance with 28 U.S.C. § 1391(c). Plaintiff Elizabeth Clarke Feher had her primary hip arthroplasty and received further medical care and treatment in Bergen County, New Jersey, and Defendants do substantial business in Bergen County, New Jersey.

Nature of the Case

3. This is an action for product liability on behalf of Plaintiffs Elizabeth Clarke Feher and Thomas Feher against Defendants who were responsible for the defective hip system implanted in Plaintiff that caused her to undergo a revision surgery to remove the defective hip system.

4. This suit is brought under the New Jersey Products Liability Act, N.J.SA. 2A:58C-1, *et seq.* ("Product Liability Act"), and common law, to recover damages and other relief including the costs of suit and reasonable attorneys' and expert fees, for the injuries Plaintiff has sustained as a result of Defendants' acts and omissions in violation of said laws.

5. Defendants knew or should have known that Durom Cup can loosen and separate from the acetabulum (hip socket) in patients such as Plaintiff, causing personal injury, significant pain, and loss of movement, and that this injury can only be remedied through subsequent revision surgery and/or hip replacement.

6. Further, Defendants misled health care professionals and the public into believing that the Durom Cup was safe and effective for use in hip replacement surgery; engaged in deceptive, misleading and unconscionable promotional or sales methods to convince health care professionals to utilize the Durom Cup, even though Defendants knew or should have known that the Durom Cup was unreasonably unsafe; and failed to warn health care professionals and the public about the safety risks of the Durom Cup.

Party Defendants

7. On information and belief, Defendants Zimmer Holdings, Inc. is a Delaware corporation with its principal place of business at 345 East Main Street, Warsaw, Indiana 46580-2746. At all relevant times, Zimmer Holdings, Inc. was the publicly traded holding company with wholly owned subsidiaries that it controlled, which designed, manufactured, marketed, promoted, and sold to distributors, physicians, hospitals, patients, and medical practitioners the Durom hip resurfacing prosthesis that is the subject of this lawsuit.

8. On information and belief, Defendants Zimmer, Inc. is a Delaware corporation with its principal place of business at 1800 West Center Street, Warsaw, Indiana 46581-0708. At all relevant times, Zimmer, Inc. was a wholly owned subsidiary of Zimmer Holdings, Inc. and the operating entity that designed, manufactured, marketed, promoted, and sold to distributors, physicians, hospitals, patients, and medical practitioners the Durom hip resurfacing prosthesis that is the subject of this lawsuit.

9. On information and belief, Defendant Zimmer Orthopaedic Surgical Products, Inc., is a Delaware corporation with its principal place of business located at 200 W. Ohio Avenue, Dover, Ohio 44622-9642 that is a wholly owned subsidiary of Zimmer, Inc. and/or Zimmer Holdings, Inc. and the operating entity that designed, manufactured, marketed, promoted, and sold to distributors, physicians, hospitals, patients, and medical practitioners the Durom hip resurfacing prosthesis that is the subject of this lawsuit.

10. At all times mentioned each of Zimmer, Inc., Zimmer Holdings, Inc. and Zimmer Orthopaedic Surgical Products, Inc. was the representative, agent, employee, joint venturer, or alter ego of each of the other entities and in doing the things alleged herein was acting within the scope of its authority as such. Specifically, each Defendant was but an instrumentality or conduit of the other in the prosecution of a single venture, namely the design, promotion, and sale of the Durom product. Therefore, it would be inequitable for any Defendants to escape liability for an obligation incurred as much for that Defendants' benefit as for the other.

11. Zimmer, Inc., Zimmer Holdings, Inc. and Zimmer Orthopaedic Surgical Products, Inc. are collectively referred to herein as "Zimmer".

12. Upon information and belief, at all relevant times, Defendants committed tortuous act(s) within the state of New Jersey out of which act(s) these causes of action arise.

Factual Allegations

13. Zimmer was founded in 1927, and purports to be a worldwide leader in the design and manufacture of orthopaedic reconstructive, spinal and trauma devices, dental implants, and related orthopaedic surgical products. Zimmer's 2008 sales exceeded $4 billion.

14. Total hip arthroplasty (THA), also called total hip replacement, is a common medical procedure performed on more than 442,000 patients in the U.S each year, according to a Millenium Research Group report issued March 2008. The surgery is designed to help relieve pain and improve joint function in people with severe hip degeneration due to arthritis or trauma.

15. The Durom Cup is a metal monoblock CoCrMo alloy cup with a coating of titanium plasma spray. It is available is sizes from 44 to 66mm, and is intended for press-fit fixation in the acetabulum, which is the cup-shaped cavity at the base of the hipbone into which the ball-shaped head of the femur fits. The Durom Cup is not cemented or screwed in place during implantation, rather the patient's bone is supposed to bond to the implant.

16. The Durom Cup was approved for use in Europe in 2003 for hip resurfacing, a procedure that requires less bone removal than conventional THA, but also uses a different surgical technique, and the Durom Cup was approved for use in the United States on or about March 2006.

17. The Durom Cup model distributed in the United States differs from the model distributed in Europe in that the coating on the Durom Cup sold in the United States has a

different structure and is thicker compared to the coating on the model sold outside the United States. Additionally, with respect to the implantation of the Durom Cup, orthopedic surgeons implanting the Durom Cup model distributed outside the United States received different training and instructions than those surgeons implanting the Durom Cup model marketed within the United States.

18. In April 2008, Dr. Lawrence Dorr, a Zimmer consultant, notified Defendants that approximately eight percent of his patients who had the Durom Cup implanted required revision surgery and that he was discontinuing use of the product.

19. On July 22, 2008, Defendants sent a letter to U.S. surgeons notifying them that it was temporarily suspending the marketing and distribution of the Durom Cup in the United States to allow it time to update product labeling to provide more detailed surgical technique instructions and to implement a surgical training program for U.S. surgeons. Although Defendants denied that the product was defective in its manufacture or design, it admitted that "additional surgical technique instructions and training are necessary in the United States, and we strongly recommend that U.S. surgeons stop implanting the Durom Cup until receiving such training."

20. In a press release dated July 22, 2008, Zimmer stated that it had reviewed data on more than 1,300 patients that had the Durom Cup implanted in the United States (approximately 10 percent of all Durom Cap procedures in the United States as of that date). Defendants further stated that where "appropriate and necessary surgical techniques" had been used, the revision rate was 1.5 percent. By contrast, the revision rate for remaining patients was 5.7 percent.

21. In a letter dated August 16, 2008, Defendants sent a letter to U.S. surgeons, providing them with updated product labeling on the Durom Cup, more detailed surgical technique instructions, and specific information regarding a comprehensive surgical training program, which Defendants stated that it developed in collaboration with several experts.

22. In addition to the labeling changes, Defendants also announced that it was launching a comprehensive surgical skills training curriculum.

23. Defendants noted that surgeons must complete at least an online training course, which reviewed the critical aspects of the Durom Cup design, preoperative planning considerations and comprehensive information regarding the critical technique steps to implant the device. This was the minimum required training to resume product use.

24. Zimmer also established Internet webcasts as follow-up to the online training, a surgical skills course that offered experience with cadavers to practice implantation of the Durom Cup in a controlled environment, and a surgeon-to-surgeon training course with one-on-one learning with an expert in the operating room.

25. From 2006 through the date of this Complaint, Defendants generally manufactured, labeled, packaged, distributed, supplied, marketed, advertised, and/or otherwise engaged in all activities that are part and parcel of the sale and distribution of a medical device, and by said activities, caused the Durom Cup to be placed into the stream of commerce throughout the United States, including New Jersey.

26. Defendants made, participated in and/or contributed to filings with the U.S. Food & Drug Administration [FDA] in conjunction with the approval process for the Durom Cup.

27. Upon information and belief Defendants controlled the design, assembly, manufacture, marketing, distribution, packaging, labeling, processing, supplying, promotion, sales, and the issuance of product warnings and related information with respect to the Durom Cup.

28. Defendants were at all times material hereto subject to the laws of the United States of America, including provisions relating to the FDA, and the rules and regulations thereof in conjunction with the approval process, labeling, and other after-market activities that pertain to the Durom Cup.

29. The Durom Cup has been widely advertised, marketed and represented by the Defendants as a safe and effective treatment.

30. From the time that Defendants first began selling the Durom Cup in the United States on or about August 16, 2008, the product labeling and product information for the Durom Cup failed to contain adequate information, instructions, and warnings concerning implantation of the product and the risks that the Durom Cup can loosen and separate from the acetabulum (hip socket) in patients.

31. Despite its knowledge of the serious injuries associated with use of the Durom Cup, Defendants engaged in a marketing and advertising program which as a whole, by affirmative and material misrepresentations and omissions, falsely and deceptively sought to create the image and impression that the use of the Durom Cup was safe.

32. Defendants downplayed and understated the health hazards and risks associated with the use of the Durom Cup and/through promotional literature as well as sales visits to orthopaedic surgeons, deceived doctors and potential users of the Durom Cup by relaying

positive information, while concealing the nature and extent of known adverse and serious health effects.

Plaintiff Elizabeth Clarke Feher's Experience With The Durom Cup

33. Prior to February 23, 2010, the treating physician for Plaintiff, as well as Plaintiff, was exposed to the aforementioned advertising and marketing campaign directly by the Defendants.

34. Plaintiff and Plaintiff's physician, either through direct promotional contact with Defendants sales representative, through word-of-mouth from other healthcare providers, and/or through promotional materials, received the information the Defendants intended that they receive, to-wit: that the Durom Cup was safe and effective for use in THA procedures.

35. On February 23, 2010 Plaintiff's physician, Dr. Mark Hartzband, performed surgery at Surgicare of Carlstadt in Carlstadt, Bergen County, New Jersey and implanted a Durom Cup in Elizabeth Clarke Feher's left hip.

36. On August 30, 2016, Plaintiff's physician, Dr. Geoffrey Westrich, performed revision surgery at the Hospital for Special Surgery, New York, New York, at which time he removed and replaced the Defective Durom Cup from Elizabeth Clarke Feher's left hip because of metallosis, the toxic effect of metal wear particles on healthy tissues.

37. As a direct and proximate result of the use of the Durom Cup, Plaintiffs suffered, and continues to suffer, serious bodily injury and harm.

38. As a direct and proximate result of the use of the Durom Cup, Plaintiffs incurred, and continues to incur, medical expenses to treat his injuries and condition.

39. At no time material to her use of the Durom Cup was Plaintiffs or her physicians told, warned, or given information about the risks of the use of the Durom Cup.

COUNT I: Products Liability Act – Failure to Warn

40. Plaintiffs repeat and incorporate by reference all other paragraphs of this Complaint as if fully set forth herein.

41. Defendants researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and otherwise released into the stream of commerce the Durom Cup and, in the course of same, directly advertised or marketed the product to the FDA, health care professionals, and consumers, or persons responsible for consumers, and therefore had a duty to warn of the risks associated with the use of the Durom Cup.

42. Defendants failed to adequately warn health care professionals and the public, including Plaintiff and his prescribing physician, of the true risks of the Durom Cup, including that the Durom Cup could loosen and separate from the hip socket, causing severe pain and injury, and requiring further treatment, including revision surgery and/or hip replacement.

43. Defendants failed to timely and reasonably warn of material facts regarding the safety and efficacy of the Durom Cup. Had Defendants done so, proper warnings would have been heeded and no health care professional, including Plaintiff's physician, would have prescribed the Durom Cup, or no consumer, including Plaintiffs, would have purchased and/or used the Durom Cup.

44. Defendants failed to timely and reasonably provide adequate instructions and training concerning safe and effective use of the Durom Cup. Had they done so,

healthcare professionals, including Plaintiff's physician, could have safely and effectively implanted the Durom Cup, without causing serious pain and injury to patients, including Plaintiff.

45. The Durom Cup, which was researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold and otherwise released into the stream of commerce by Defendants, was defective due to inadequate post-marketing warnings and/or instruction because, after Defendants knew or should have known that there was reasonable evidence of an association between the Durom Cup and THA failure causing serious injury and pain, Defendants failed to provide adequate warnings to health care professionals and the consuming public, including Plaintiffs, and continued to aggressively promote the Durom Cup.

46. Defendants failed to perform or otherwise facilitate adequate testing; failed to reveal and/or concealed testing and research data; and selectively and misleadingly revealed and/or analyzed testing and research data.

47. As a direct and proximate result of the conduct of Defendants as aforesaid, Plaintiffs Elizabeth Clarke Feher suffered serious and permanent non-economic and economic injuries.

WHEREFORE, Plaintiffs demands judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT II: Products Liability Act - Defective Design

48. Plaintiffs repeat and incorporate by reference all other paragraphs of this Complaint as if fully set forth herein.

49. Defendants are the researcher, developer, manufacturer, distributor, marketer, promoter, supplier and seller of the Durom Cup, which is defective and unreasonably dangerous to consumers.

50. The Durom Cup is defective in its design or formulation in that it is not reasonably suitable or safe for its intended purpose and/or its foreseeable risks exceed the benefits associated with its design and formulation. The Durom Cup is defective in design or formulation in that it lacks efficacy and/or it poses a greater likelihood of injury than other hip replacement devices and similar hip replacement devices on the market and is more dangerous than ordinary consumers can reasonably foresee.

51. If the design defects were known at the time of manufacture, a reasonable person would have concluded that the utility of the Durom Cup did not outweigh the risk of marketing a product designed in that manner.

52. The defective condition of the Durom Cup rendered it unreasonably dangerous and/or not reasonably safe, and the Durom Cup was in this defective condition at the time it left the hands of the Defendants. The Durom Cup was expected to and did reach consumers, including Plaintiffs, without substantial change in the condition in which it was designed, manufactured, labeled, sold, distributed, marketed, promoted, supplied and otherwise released into the stream of commerce.

53. Plaintiffs were unaware of the significant hazards and defects in the Durom Cup. The Durom Cup was unreasonably dangerous and/or not reasonably safe in that it was

more dangerous than would be reasonably contemplated by the ordinary user. During the period that Plaintiffs used the Durom Cup, it was being utilized in a manner that was intended by Defendants. At the time Plaintiffs received and used the Durom Cup, it was represented to be safe and free from latent defects.

54. Defendants are strictly liable to Plaintiffs for designing, manufacturing, and placing into the stream of commerce a product which was unreasonably dangerous for its reasonably foreseeable uses at the time it left the control of Defendants because of the design defects.

55. Defendants knew or should have known of the danger associated with the use of the Durom Cup, as well as the defective nature of the Durom Cup, but has continued to design, manufacture, sell, distribute, market, promote and/or supply the Durom Cup so as to maximize sales and profits at the expense of public health and safety, in conscious disregard of the foreseeable harm caused by the Durom Cup.

56. As a direct and proximate cause of the design defect and Defendants' misconduct as set forth herein, Plaintiffs has suffered and continues to suffer serious and permanent non-economic and economic injuries.

WHEREFORE, Plaintiffs demands judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT III: Breach of Express Warranty

57. Plaintiffs repeat and incorporate by reference all other paragraphs of this Complaint as if fully set forth herein.

58. Defendants advertised, labeled, marketed and promoted its product, the Durom Cup, representing the quality to health care professionals, the FDA, Plaintiffs, and the public in such a way as to induce its purchase or use, thereby making an express warranty that the Durom Cup would conform to the representations. More specifically, Defendants represented that the Durom Cup was safe and effective, that it was safe and effective for use by individuals such as Plaintiffs, and/or that it was safe and effective to treat Plaintiffs' condition.

59. The representations, as set forth above, contained or constituted affirmations of fact or promises made by the seller to the buyer which related to the goods and became part of the basis of the bargain creating an express warranty that the goods shall conform to the affirmations of fact or promises.

60. The Durom Cup did not conform to the representations made by Defendants in that the Durom Cup was not safe and effective, was not safe and effective for use by individuals such as Plaintiffs, and/or was not safe and effective to treat individuals, such as Plaintiffs.

61. At all relevant times, Plaintiffs used the Durom Cup for the purpose and in the manner intended by Defendants.

62. Plaintiffs and Plaintiffs' physician, by the use of reasonable care, would not have discovered the breached warranty and realized its danger.

63. The breach of the warranty was a substantial factor in bringing about Plaintiffs' injuries.

64. As a direct result of Defendants' conduct as aforesaid, Plaintiffs suffered and continues to suffer serious and permanent non-economic and economic injuries.

WHEREFORE, Plaintiffs demands judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT IV: Products Liability Act - Breach of Implied Warranty

65. Plaintiffs repeat and incorporate by reference all other paragraphs of this Complaint as if fully set forth herein.

66. The Durom Cup was not reasonably fit for the ordinary purposes for which such goods are used and did not meet the expectations for the performance of the product when used in the customary, usual and reasonably foreseeable manner, nor was the Durom Cup minimally safe for its expected purpose.

67. At all relevant times, Plaintiffs used the Durom Cup for the purpose and in the manner intended by Defendants.

68. Plaintiffs and Plaintiffs' physician, by the use of reasonable care would not have discovered the breached warranty and realized its danger.

69. The breach of the warranty was a substantial factor in bringing about Plaintiffs' injuries.

70. As a direct result of Defendants' conduct as aforesaid, Plaintiffs has suffered and continues to suffer serious and permanent non-economic and economic injuries.

WHEREFORE, Plaintiffs demands judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT V: Punitive Damages Under Common Law and the Products Liability Act

71. Plaintiffs repeat and incorporate by reference all other paragraphs of this Complaint as if fully set forth herein.

72. Plaintiffs are entitled to punitive damages because the Defendants' wrongful acts and/or omissions were wanton or in conscious disregard of the rights of others. The Defendants misled both the medical community and the public at large, including Plaintiffs herein, by making false representations about the safety and efficacy of the Durom Cup and by failing to provide adequate instructions and training concerning its use. Defendants downplayed, understated, and/or disregarded their knowledge of the serious and permanent side effects and risks associated with the use of the Durom Cup despite available information demonstrating that the Durom Cup could loosen and separate, causing serious harm to patients. Such risks and adverse effects could easily have been avoided had Defendants not concealed knowledge of the serious and permanent side effects and risks associated with the use of the Durom Cup or provided proper training and instruction to physicians regarding use of the Durom Cup. Defendants' misrepresentations included knowingly withholding material information from the FDA, the medical community and the public, including Plaintiffs, concerning the safety of the Durom Cup.

73. Defendants were or should have been in possession of evidence demonstrating that the Durom Cup caused serious side effects. Nevertheless, Defendants continued to market the Durom Cup by providing false and misleading information with regard to its safety and efficacy.

74. Defendants failed to provide warnings that would have dissuaded health care professionals from using the Durom Cup, thus preventing health care professionals and consumers, including Plaintiffs, from weighing the true risks against the benefits of using the Durom Cup.

75. Defendants failed to provide adequate training and instructions to physicians that could have prevented failure of the Durom Cup causing serious harm and suffering to patients, including Plaintiffs.

WHEREFORE, Plaintiffs demands judgment against Defendants for compensatory damages and punitive damages, together with interest, costs of suit and attorneys' fees and such other relief as the Court deems proper.

COUNT VI: Loss of Consortium

76. Plaintiffs repeat and incorporate by reference all other paragraphs of this Complaint as if

fully set forth herein.

77. Plaintiff Thomas Feher is the lawful husband of Plaintiff Elizabeth Clarke Feher.

78. As a result of the injuries Defendants' wrongful conduct caused to her husband, Plaintiff

has suffered injuries in the form of loss of care, comfort, affection, consortium, and services.

WHEREFORE, Plaintiffs demands judgment against Defendants for compensatory damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

Relief Requested

WHEREFORE, Plaintiffs prays for judgment as follows:

a. Awarding actual damages to Plaintiffs incidental to his purchase and use of the Durom Cup prosthesis in an amount to be determined at trial;

b. Awarding treble and/or punitive damages to Plaintiffs;

c. Awarding pre-judgment and post-judgment interest to Plaintiffs;

d. Awarding the costs and expenses of this litigation to Plaintiffs;

e. Awarding reasonable attorneys' fees and costs to Plaintiffs as provided by law;

and

f. Granting such other relief as the Court deems necessary, just and proper.

Jury Demand

Plaintiffs demand a trial by jury on all issues raised in the various Counts of the Complaint.

Dated: September 21, 2016

/s/ Terrence Smith
Terrence Smith
Davis, Saperstein & Salomon, P.C.
375 Cedar Lane
Teaneck, New Jersey 07666
201-907-5000
201-692-0444 fx
tsmith@dsslaw.com
Attorneys for Plaintiff